

K 96 00 32

APR - 1 1996

**Attachment 27**  
**510(k) Summary Statement for the**  
**Coherent VersaPulse Aesthetic Surgical Lasers**

**I. General Information**

Submitter: Coherent Medical Group  
3270 West Bayshore Road  
Palo Alto, CA 94303

Contact Person: Anne C. Worden

Summary Preparation Date: December 29, 1995

**II. Names**

Device Names: Coherent VersaPulse Aesthetic Surgical Lasers and Delivery Accessories.

Primary Classification Name: Laser Powered Surgical Instrument (and Accessories).

**III. Predicate Devices**

- Laserscope Orion SL Series & KTP/532, KTP:YAG Surgical Lasers (K941841, K933880 & K911830)
- Continuum Biomedical Medlite 532 & 1064 nm Surgical Lasers (K952636, K922935 & K922577)
- Continuum Biomedical MedAlex 755 nm Surgical Lasers (K935631)
- Candela TL-1 Alexandrite Laser (K944090 & K940173)
- Pfizer/Premier Centauri & Pegasus 2940 nm Surgical Lasers (K905802 & K904627)
- Continuum Multilite Er:YAG (755 nm) Surgical Laser (K933057)
- Laserscope SmartScan Fiber Delivery Device for use with Orion SL Series & KTP/532, KTP:YAG Surgical Lasers (K941841, K933880 & K911830)
- Candela 10 mm Circular Spot Laser Handpiece (K950661)
- Coherent Family of Scanner Handpieces for use with Coherent ULTRAPULSE Carbon Dioxide Surgical Lasers (K951812 & K946304)
- Cyrus Chess Cool Laser Optics (CLO) Unit for use with Argon (488/514 nm), Argon/Dye (577 nm and 585 nm), and KTP (532 nm) Surgical Lasers (K934486)

**IV. Product Description**

The Coherent VersaPulse Aesthetic Surgical Lasers (and its delivery accessories) are intended to be used to deliver: frequency doubled, Q-switched frequency doubled, and Q-switched Nd:YAG; Q-switched Alexandrite:YAG laser energy for use in surgical applications requiring the photothermolysis (photocoagulation) of soft tissue; and Er:YAG laser energy for use in surgical applications requiring the excision, incision, ablation, vaporization, and coagulation of soft tissue in medical specialties including: general and plastic surgery; and dermatology. Coherent VersaPulse Aesthetic Surgical Lasers are comprised of the following main components:

- a laser console and tower;
- a counterbalanced articulated arm and delivery systems;
- a fiber port and delivery systems;
- control and display panels;
- footswitch and handswitch delivery controls;
- a remote control unit; and
- a variety of delivery device accessories (articulated arm and fiber handpieces, scanners, and epidermal cooling devices).

## **V. Indications for Use**

The Coherent VersaPulse Aesthetic Surgical Lasers and the Delivery Accessories that are used with them to deliver 532 nm, 1064 nm and 755 nm laser energy that are indicated for use in surgical applications requiring photothermolysis of soft tissue, and 2940 nm laser energy that is indicated for use in surgical applications requiring excision, incision, ablation, vaporization, and coagulation of soft tissue in medical specialties including: general and plastic surgery; and dermatology.

## **VI. Rationale for Substantial Equivalence**

The Coherent VersaPulse Aesthetic Surgical Lasers and their delivery device accessories share the same indications for use, similar design features (including control system, wavelengths, beam quality, laser tube configuration, active medium, cooling system, and controls and displays), functional features (including power, repetition rate, energy, spot sizes and treatment areas), and therefore are substantially equivalent to the Laserscope Orion SL Series & KTP/532, KTP:YAG Surgical Lasers (K941841, K933880 & K911830), the Continuum Biomedical Medlite 532 nm & 1064 nm Surgical Lasers (K952636, K922935 & K922577), the Continuum Biomedical MedAlex 755 nm Surgical Lasers (K935631), the Candela TL-1 Alexandrite Surgical Lasers (K944090 & K940173), the Pfizer/Premier Centauri & Pegasus 2940 nm Surgical Lasers (K905802 & K904627), and the Continuum Multilite Er:YAG Surgical Laser (K933057), and to the Laserscope SmartScan Fiber Delivery Device for use with Orion SL Series & KTP/532, KTP:YAG Surgical Lasers (K941841), the Candela 10 mm Circular Spot Laser Handpiece (K950661), the Coherent Family of Scanner Handpieces for use with Coherent ULTRAPULSE Carbon Dioxide Surgical Lasers (K951812 & K946304), as well as the Cyrus Chess Cool Laser Optics (CLO) Unit for use with Argon (488/514 nm), Argon/Dye (577 nm and 585 nm), and KTP (532 nm) Surgical Lasers (K934486).

## **VII. Safety and Effectiveness Information**

In-vivo testing (was performed to demonstrate that the laser energy provided by the Coherent VersaPulse Aesthetic Surgical Lasers is equivalent to that provided by the currently marketed surgical lasers. Testing is performed to establish the biocompatibility of new delivery device materials that could potentially contact patient tissue.

## **VIII. Conclusion**

The Coherent VersaPulse Aesthetic Surgical Lasers were found to be substantially equivalent to similar currently marketed surgical laser devices. The Coherent VersaPulse Aesthetic Surgical Lasers share the same indications for use, similar design features, and similar functional features as the currently marketed Surgical Lasers and delivery devices. The physical test results demonstrated that the Coherent VersaPulse Aesthetic Surgical Lasers have acceptable performance characteristics.